MAY - 1 2012 K112593

4100 E. Milham Avenue
Kalamazoo, MI 49001
t: 269 323 7700 f: 269 389 5412
www.stryker.com

stryker®
Instruments

510(k) Summary

510(k) Owner:	Stryker Instruments 4100 E. Milham Avenue Kalamazoo, MI 49001 (p) 269-323-7700 (f) 269-389-5412
Contact Person:	Michelle Jump
Registration No.:	1811755
Trade Name:	Stryker® Consolidated Operating Room Equipment (CORE) System
Common Name:	Console
Classification Name and Regulation Number	**Primary Product Code**

PRODUCT CODE	DEVICE	REGULATION NUMBER	CLASS	REVIEW PANEL
ERL	Drill, surgical, ent (electric or pneumatic) including handpiece	21 CFR 874.4250	II	EAR, NOSE & THROAT

Secondary Product Codes

PRODUCT CODE	DEVICE	REGULATION NUMBER	CLASS	REVIEW PANEL
DZI	Drill, bone, powered	21 CFR 872.4120	II	DENTAL
DZJ	Driver, wire, and bone drill, manual	21 CFR 872.4120	II	DENTAL
HBE	Drills, burrs, trephines & accessories (simple, powered)	21 CFR 882.4310	II	NEUROLOGY

Predicate Devices:	Stryker® Consolidated Operating Room Equipment (CORE) System (K040300, K040369, K032303); Synthes Electric Pen Drive (EPD) System (K043310); and Stryker® Total Performance System (K032117, K942956, K943589, K943569, K943540)
Device Description:	The Stryker Consolidated Operating Room Equipment (CORE) System is an electrically powered system. This system includes a console, irrigation accessories, footswitches, handswitches, and handpiece cords which drive a variety of devices

	including saws, drills, wire drivers, microdebriders, and bone mills.
Indications for Use:	The Stryker ® Consolidated Operating Room Equipment (CORE) System is intended for use in the cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to dental, ENT (ear, nose, throat), neuro, spine, and endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.
Testing	The clarification of the Stryker® Consolidated Operating Room Equipment (CORE) System indications for use statement is not the result of any design changes that have been made to the console. In addition, the use of this device in orthopedic and spine applications do not present any new risks that would require testing. Therefore, no additional performance testing was performed to evaluate this change. Each software revision of the Stryker® CORE Console has undergone a code review by a team of internal experts to review source code, evaluate error messaging, and verify adherence to standards. An analysis of new hazards and software requirements emerging as a result of the changes is evaluated for each revision. This is documented in the CORE Console's Software Requirements Specifications (SRS) and risk analysis, which can be found in Section 16. Subsequent verification/ validation testing, including system and Unit box testing, is performed on the console to confirm the continued safety and effectiveness of the Stryker® CORE Console prior to the release of each software revision to the market. The results of this testing demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device.
Biocompatibility	Per ISO 10993 – 1:2003 and FDA G95-1:1995 guidelines, a biocompatibility evaluation for the CORE Console is not required due to the non-patient contact intended use of this medical device.
Substantial Equivalence (SE) Rationale:	The Stryker ® Consolidated Operating Room Equipment (CORE) System when compared to its predicates has a similar intended use and technology characteristics as the predicate devices. Therefore, this device is substantially equivalent to predicate devices.

Predicate Device Comparison Table

Element of Comparison	Stryker ® CORE Console (Under Review)	Stryker ® System (K040300, K040369, K032303)	Synthes Electric Pen Drive (EPD) System (K043310)	Stryker ® Total Performance System (TPS) (K942956, K943589, K943569, K943540, K032117)	Substantial Equivalence
Indications for Use	The Stryker ® Consolidated Operating Room Equipment (CORE) Console is intended for use in the cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to dental, ENT, neuro, spine, and endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and	The Stryker® Consolidated Operating Room Equipment (CORE) System is intended for use in the cutting, drilling, reaming, decorticating, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to dental, ENT, neuro, and endoscopic	The Synthes Electric Pen Drive (EPD) System is indicated for screw insertion, pin and wire placement, cutting of bone and metal, drilling, reaming, decorticating, shaping, and smoothing of bones and teeth in a wide variety of surgical procedures, including but not limited to general orthopedic trauma, foot, hand, maxifacial, neurosurgical, oral, otolaryngological,	The Stryker ® Total Performance System is intended for use in the cutting, drilling, reaming, decorticating, and smoothing of bone, teeth and other bone related tissue in a variety of surgical procedures, including but not limited to dental, ENT, neuro and endoscopic. It is also usable in the placement or cutting of screws, wires, pins, and other fixation	The indications for use for all three devices are similar.

	other fixation devices.	applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.	reconstructive and spine surgery.	devices. It can also be used to cut metal.	
Handpiece Connectors	Three connectors allow handpiece cords to be connected to the console. The console is capable of running two handpieces simultaneously.	Three connectors allow handpiece cords to be connected to the console. The console is capable of running two Handpieces simultaneously.	Two connectors allow for two Electric Pen Drive units to be connected.	Three connectors allow handpiece cords to be connected to the console.	Similar for all three devices. Design feature is identical to previously-cleared Stryker® CORE Console.
Footswitch Connectors	Two connectors allow up to two footswitches to be run on the console simultaneously. The console can also be controlled by a wireless footswitch.	Two connectors allow up to two footswitches to be run on the console simultaneously.	One connector allows one footswitch to control one drive unit.	One connector allows one footswitch to control one drive unit.	Similar for all three devices. Stryker® CORE Console under review has the capability of connecting to a wireless footswitch.
Adjustable Operating Parameters	The LCD screen allows the user to set the desired operating parameters. Operating parameters are also obtained from attached accessories.	The LCD screen allows the user to set the desired operating parameters. Operating parameters are also obtained from attached accessories.	Max speed may be controlled using slide controls provided in the console for each drive unit. Torque limiting feature can be controlled using an On/ Off/Calibrate knob. Irrigation can be used with either Drive Unit 1 or Drive Unit 2 and knob control is available to select between continuous and variable irrigation for each drive unit. Irrigation flow can be controlled using a flow rate adjustment knob. OR User sets the operating parameters using the controls available in the console or using the handswitch or footswitch interface.	The LCD screen allows the user to set the desired operating parameters.	TPS and CORE Console have similar software feature. Design feature is identical to previously-cleared Stryker® CORE Console.
Power Output	400 Watts	400 Watts	Information not available.	400 Watts	TPS and CORE Console power output is identical. Design feature is identical to previously-cleared Stryker® CORE Console.
Wireless Tag Technology	Accessories are recognized and identified on the console screen.	Accessories are recognized and identified on the console screen.	Information not available.	Accessories are recognized and identified on the console screen.	TPS and CORE Console have similar software feature. Design feature is identical to previously-cleared Stryker® CORE Console.
Torque Control	Mechanism to allow the user to specify the torque profile to be used for handpieces.	N/A	Mechanism to allow the surgeon to implant and tighten screws under power. The user calibrates and sets the desired torque value using the control available in the console.	N/A	The Stryker® CORE Console and Synthes Electric Pen Drive System torque control features are similar. Both devices allow the user to vary torque settings.

Console Accessories	Irrigation accessories Handpiece cord Handswitch Footswitch	Irrigation accessories Handpiece cord Handswitch Footswitch	Irrigation accessories Handpiece cord Handswitch Footswitch	Irrigation accessories Handpiece cord Handswitch Footswitch	Similar for all three devices.

Safety and Effectiveness:	Based upon the comparison to the predicate devices, the Stryker® Consolidated Operating Room Equipment (CORE) System does not raise any new issues of safety and effectiveness and is substantially equivalent to legally marketed devices.
Submitted by:	Michelle Jump Senior Regulatory Affairs Representative  Signature
Date Submitted:	May 1, 2012

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY - 1 2012

Stryker Corporation
% Ms. Michelle Jump
4100 E. Milham Avenue
Kalamazoo, MI 49001

Re: K112593
Trade/Device Name: Stryker® Consolidated Operating Room Equipment (CORE) System
Regulation Number: 21 CFR 874.4250
Regulation Name: Ear, nose, and throat electric or pneumatic surgical drill
Regulatory Class: Class II
Product Code: ERL
Dated: April 24, 2012
Received: May 1, 2012

Dear Ms. Jump:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(K) Number: K112593

Device Name: Stryker® Consolidated Operating Room Equipment (CORE) System

Indications for Use:

The Stryker ® Consolidated Operating Room Equipment (CORE) System is intended for use in the cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to, dental, ENT (ear, nose, throat), neuro, spine, and endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.

Prescription Use: X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

ption Use _____
21 CFR 801.109)

510(k) Number K112593

Prescription Use X
(Per 21 CFR 801.109)